

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0876565	(X3) Date Survey Completed 12/21/2021
Name of Provider or Supplier Care Station Medical Group	Street Address, City, State 328 West St Georges Ave, Linden, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Laboratory Manager (LM), the Laboratory Director failed to sign attestation statements for the 2020 and 2021 Hematology/Coagulation and Chemistry Core events with the American Proficiency Institute (API). The LM confirmed on 12/21/21 at 10:00 am that PT records were not maintained.</p>
D6013	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance</p>

characteristics of the method;

This STANDARD is not met as evidenced by:

Based on surveyor review of the Linearity/Calibration Verification (CV) report and interview with the Laboratory Manager (LM), the Laboratory Director (LD) failed to ensure that CV procedures performed on the Abbott Architect c 4000 analyzer were adequate on 1/10/20. The findings include: 1. The LD did not review and sign the CV results. 2. The LM confirmed on 12/21/21 at 11:00 am that CV records were not adequate.